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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,703	09/26/2001	Subba Reddy Palli	A01020B	8135
7590 05/14/2004				
RheoGene Holding Inc 2650 Eisenhower Avenue Norristown, PA 19403		EXAMINER MURPHY, JOSEPH F		
		ART UNIT PAPER NUMBER 1646		
DATE MAILED: 05/14/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/965,703	PALLI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Joseph F Murphy	1646	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 8-10, 13, 14 and 16-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 11-12 is/are rejected.
- 7) ☒ Claim(s) 7 and 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>070502 070302</u> . | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1646

**DETAILED ACTION*****Election/Restrictions***

Applicant's election with traverse of Group III, drawn to drawn to a gene expression modulation system comprising two expression vectors wherein the LBD of the first polypeptide is encoded by SEQ ID NO: 3 in the reply filed 3/2/2004 is acknowledged. The traversal is on the ground(s) that the groups designated by the Examiner fail to define products with properties so distinct as to warrant separate examination and search and that the present claims represent a web of knowledge and continuity of effort that merits examination in a single application, and that there would not be an undue burden to search all the claims. This is not found persuasive because Applicant's attention is directed to MPEP 808.02 which states that "Where the related inventions as claimed are shown to be distinct under the criteria of MPEP 806.05 (c-i), the examiner, in order to establish reasons for insisting upon restriction, must show by appropriate explanation one of the following: (A) Separate classification thereof; (B) A separate status in the art when they are classifiable together; (C) A different field of search." Here, the sequences are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function, and each has an independent utility, that is distinct for each invention which cannot be exchanged. The databases that must be searched are large, and growing continuously. Thus, there is a burden on the Office to search multiple sequences that differ substantially in structure and function.

Claims 1-7, 11-12, 15 read on the elected invention and are under consideration. Claims 8-10, 13-14, 16-36 are withdrawn from consideration pursuant to 37 CFR 1.142(b).

The requirement is still deemed proper and is therefore made FINAL.

### ***Specification***

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention.

Applicant should avoid the use of novel in the title, as patents are presumed to be novel and unobvious.

The abstract of the disclosure is objected to because it is entitled "Abstract of the Invention". Pursuant to 37 CFR 1.72 a brief abstract of the technical disclosure in the specification must commence on a separate sheet, preferably following the claims, under the heading "Abstract" or "Abstract of the Disclosure". Correction is required. See MPEP § 608.01(b).

### ***Claim Objections***

Claims 7-10, 13-16 are objected to because of the following informalities: They contain limitations drawn to non-elected subject matter. Appropriate correction is required.

Claim 1 is objected to because there are two subheadings labeled "(a)(i)". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3 are rejected under 35 U.S.C. 102(a) as being anticipated by Martinez et al. (1999).

The instant claims are drawn to a gene expression modulation system wherein the first gene expression vector comprises a DBD and an LBD, wherein the LBD is an ecdysone receptor (EcR) LBD; and a second gene expression vector which comprises a transactivation domain and an LBD not from USP. The gene expression system must also comprise a reporter gene vector comprising a response element to the DBD of the first vector. These claims are anticipated by the Martinez reference because the Martinez reference teaches an inducible gene expression system comprising three vectors, the first of which comprises the GR DBD and EcR LBD (page 547 paragraph bridging column 1 and 2). The second vector comprises the VP16 transactivation domain along with EcR LBD. The reporter gene construct comprises the GR response element, the CaMV promoter and a reporter gene (beta-glucuronidase) page 547, column 2, third paragraph; also see page 548, Figure 1).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

Art Unit: 1646

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martinez et al. (1999) in view of U.S. 59191667 (Gage et al.).

The instant claims are drawn to a gene expression modulation system wherein the first gene expression vector comprises a DBD and an LBD, wherein the LBD is an ecdysone receptor (EcR) LBD; and a second gene expression vector which comprises a transactivation domain and an LBD not from USP. The gene expression system must also comprise a reporter gene vector comprising a response element to the DBD of the first vector. These claims are unpatentable because the Martinez reference teaches an inducible gene expression system comprising three vectors, the first of which comprises the GR DBD and EcR LBD (page 547 paragraph bridging column 1 and 2). The second vector comprises the VP16 transactivation domain along with EcR LBD. The reporter gene construct comprises the GR response element, the CaMV promoter and a reporter gene (beta-glucuronidase) page 547, column 2, third paragraph; also see page 548, Figure 1). The Martinez reference does not teach the gene expression system wherein the second LBD is from RXR. However, the '667 patent discloses a transgenic animal contains one or more expression constructs containing nucleic acid encoding an ecdysone receptor, exogenous RXR, and an heterologous gene under the transcription control of an ecdysone response element.

Art Unit: 1646

Therefore, it would have been obvious to one of skill in the art at the time the invention was made to make

a gene expression modulation system wherein the first gene expression vector comprises a DBD and an LBD, wherein the LBD is an ecdysone receptor (EcR) LBD; and a second gene expression vector which comprises a transactivation domain and an LBD not from USP; and a reporter gene vector comprising a response element to the DBD of the first vector, wherein the gene expression system comprises an ecdysone receptor and an exogenous RXR. The motivation is provided in in transgenic mice containing an ecdysone response element and expressing ecdysone receptor and RXR, muristerone treatment can activate gene expression. Thus, with tissue specific expression of ecdysone receptor and RXR and timely hormone treatment, inducible gene expression can be achieved with spatial, dosage, and temporal specificity.

### ***Conclusion***

Claims 1-6, 11-12 are rejected.

Claims 7, 15 are objected.

### ***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Murphy whose telephone number is (571) 272-0877. The examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272-0871.

Art Unit: 1646

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'J. Murphy', with a long, sweeping horizontal stroke extending to the right.

Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
May 2, 2004